FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

KING PHARMACEUTICALS, INC.; KING PHARMACEUTICALS RESEARCH AND DEVELOPMENT, INC.; and WYETH Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	Civil Action No. 05-3855 (JAP) **OPINION**

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PISANO, District Judge.

I. INTRODUCTION

Plaintiffs King Pharmaceuticals, Inc. ("King Pharma") and King Pharmaceuticals Research and Development, Inc. ("King R&D") (together, "King"), as well as involuntary Plaintiff Wyeth,[1] brought this action for patent infringement against Defendant Teva Pharmaceuticals USA, Inc. ("Teva"). King alleges that Teva has infringed one or more claims of United States Patent No. 4,626,538 ("the '538 Patent"), owned by Wyeth, under which King R&D has exclusive license and King Pharma exclusive sub-license to sell zaleplon drug products in the United States. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). Teva has moved to dismiss the Complaint, arguing that the '538 Patent expired on June 23, 2003 as a matter of law and that, because no valid and enforceable patent is being asserted, the Complaint fails to state a claim for relief. For the reasons expressed below, the Court denies Teva's motion to dismiss.

II. BACKGROUND

This is a patent infringement action commenced by King against Teva under the '538 Patent.[2] Wyeth is the owner of the '538 Patent. (Compl. ¶ 13). King R&D has an exclusive license, *inter alia*, to sell, by prescription, zaleplon drug products in the United States under the '538 Patent. (Compl. ¶ 14). King Pharma has an exclusive sub-license to sell such products.

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[1] King named Wyeth as an involuntary plaintiff to this action pursuant to Fed. R. Civ. P. 19.

[2] The '538 Patent is entitled "[7-(3-Disubstituted Amino)Phenyl]Pyrazolo[1,5-a]Pyrimidines." (Compl. ¶ 9; Compl. Ex. A).

King Pharma sells in the United States, by prescription, drug products containing zaleplon under the trademark Sonata®, which is used to treat insomnia. (Compl. ¶ 14; King's Br. at 3). An FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book")[3] lists the '538 Patent as being applicable to King's Sonata® drug products. (Compl. ¶ 16).

From the Complaint and the motion papers, the Court understands the history of the '538 Patent to be as follows. The '538 Patent was issued on December 2, 1986. (Compl. ¶ 9; Compl. Ex. A). The '538 Patent is subject to a terminal disclaimer. (Compl. Ex. A). The application for what ultimately became the '538 Patent was initially rejected on the ground that it claimed the same invention that was claimed in an earlier patent, U.S. Patent No. 4,521,422 ("the '422 Patent"), and the '538 Patent was granted only after the applicant filed a terminal disclaimer under 35 U.S.C. § 253.[4] (Teva Br. at 2). This terminal disclaimer disclaimed any term of the '538 Patent that would otherwise have extended beyond the '422 Patent, which expired on June 23, 2003. (Teva Br. at 2). The original termination date of the '422 Patent was June 3, 2002 (seventeen years from its issue date); however, pursuant to 35 U.S.C. § 154, this date was reset to June 23, 2003 (twenty years from its filing date). (Teva Br. at 5). The United States Patent and Trademark Office (the "PTO") agreed that the '538 Patent's expiration date should be reset at June 23, 2003 as well since the term of the '538 Patent was linked to the term of the '422 Patent.

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[3] The FDA's Orange Book is "a register that provides notice of patents covering name brand drugs." *Pharmacia Corp. v. Par Pharm.*, 417 F.3d 1369, 1370 (Fed. Cir. 2005).

[4] Teva also refers to the existence of a third patent application, which ultimately issued as U.S. Patent No. 4,654,347, that was a "sister" to the application that issued as the '538 Patent. (Teva Br. at 2, 4 n.2).

(Teva Br. at 2). Thus, based on the terminal disclaimer, the '538 Patent had been scheduled to expire on June 23, 2003. (King's Br. at 3; Teva's Br. at 1-2).

However, on June 4, 2003, pursuant to 35 U.S.C. § 156, the PTO extended the term of the '538 Patent for a period of 1810 days, running from June 23, 2003, based on the regulatory review of the product Sonata® (zalephon) by the FDA (the "Patent Term Extension"). (Compl. ¶ 10; Compl. Ex. B). Based on the Patent Term Extension, the expiration date of the '538 Patent became June 6, 2008. (Compl. ¶ 8).

This action relates to an Abbreviated New Drug Application ("ANDA") filed by Teva with the United Stated Food and Drug Administration ("FDA") for approval to market generic versions of King's Sonata® drug products ("ANDA No. 77-239"). (Compl. ¶¶ 1, 15). In a June 20, 2005 notification letter Teva sent to King and Wyeth, Teva stated that it had submitted ANDA No. 77-239 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of capsules of zaleplon. (Compl. ¶¶ 15, 16). King alleges on information and belief that ANDA No. 77-239 indicates that the zaleplon capsules Teva seeks to market are bioequivalent to King's Sonata® drug products, have the same active ingredient, administration, dosage form, and strength as King's Sonata® drug products, and have the same, or substantially the same, proposed labeling as King's Sonata® drug products. (Compl. ¶ 18).

King filed its Complaint on August 2, 2005, alleging that Teva's ANDA filing constitutes patent infringement and that, if the FDA approves Teva's ANDA filing, Teva will infringe the '538 Patent by making, using, offering to sell, importing, and selling its zaleplon capsules in the United States. (Compl. ¶ 20-21). King seeks a declaratory and injunctive relief, damages, attorneys' fees, and costs and expenses. On September 22, 2005, Teva moved to dismiss the

Complaint for failure to state a claim upon which relief can be granted. The Court heard oral argument on Teva's motion on December 20, 2005. The crux of Teva's argument is that the term of a terminally disclaimed patent may not be extended under 35 U.S.C. § 156 and, therefore, the '538 Patent expired on June 23, 2003.

III. STANDARD OF REVIEW

Teva argues that the '538 Patent expired on June 23, 2003 as a matter of law and that, because no valid and enforceable patent is being asserted, the Complaint fails to state a claim for relief. Under Federal Rule of Civil Procedure 12(b)(6), a defendant may file a motion to dismiss for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). A complaint should not be dismissed "unless plaintiff can prove no set of facts that would entitle [plaintiff] to relief" and "it appears beyond doubt that 'the facts alleged in the complaint, even if true, fail to support the claim.'" *Gaines v. Sarlo*, No. 03-2688 (GEB), 2005 WL 1241973, at *1-2 (D.N.J. May 25, 2005) (quoting *Ransom v. Marrazzo*, 848 F.2d 398, 401 (3d Cir. 1988)); *see also Hishon v. King & Spaulding*, 467 U.S. 69, 73 (1984) (noting that a motion under Rule 12(b)(6) may be granted if it is beyond any doubt "that no relief could be granted under any set of facts that could be proved consistent with the allegations"). In deciding a Rule 12(b)(6) motion to dismiss, a court must "accept the allegations in the complaint as true, and draw all reasonable factual inferences in favor of the plaintiff." *Turbe v. Gov't of the V.I.*, 938 F.2d 427, 428 (3d Cir. 1991). However, "[l]egal conclusions offered in the guise of factual allegations. . . are given no presumption of truthfulness." *Kirkland v. Morgievich*, No. 04-1651 (WGB), 2005 WL 3465669, at *1 (D.N.J. Dec. 19, 2005). The court must not consider "whether the plaintiffs will ultimately

prevail, only whether they are entitled to offer evidence to support their claims." *Saint-Gobain Performance Plastics Corp., HCM Div. v. Truseal USA, Inc.*, 351 F.Supp.2d 290, 293 (D.N.J. 2005) (quotations and citations omitted).

IV. DISCUSSION

A. The Parties' Arguments

Teva's allegation that the '538 Patent expired on June 23, 2003 as a matter of law is premised on the argument that the term of a patent subject to a terminal disclaimer under 35 U.S.C. § 253 may not be extended under 35 U.S.C. § 156. Section 156 provides for a patent term extension in specified circumstances when delay has occurred during the FDA regulatory review process for approving a drug for sale. *See* 35 U.S.C. § 156 (2005). Section 253 provides that a patentee or applicant may disclaim an entire term, or the terminal part of a term, of a patent or patent to be granted. *See* 35 U.S.C. § 253 (2005). Teva argues that this case implicates fundamental patent law principles including that "the inventor can have but a single valid patent for his invention" and that "when the right to exclude granted by a patent expires at the end of the patent term, the public shall be free to use the invention as well as obvious modifications thereof." (Teva Br. at 10, 12 (citing *Odiorne v. Amesbury Nail Factory*, 18 F. Cas. 578, 579 (Cir. Cr. D. Mass. 1819); *In re Robeson*, 331 F.2d 610, 614 (C.C.P.A. 1964))). Teva argues that § 156 and § 253 are in conflict because "a terminal disclaimer prevents a second patent claiming an obvious variant from extending beyond the life of an earlier patent", and that granting a § 156 extension to a patent subject to a § 253 terminal disclaimer would "eviscerate[] the settled law prohibiting double patenting and the legal effect of a terminal disclaimer." (Teva Br. at 12, 15).

Teva argues that § 156 did not alter the settled law of terminal disclaimers and makes a number of statutory construction arguments to support the proposition that § 156 cannot be construed to permit terminally disclaimed patents from obtaining a § 156 extension. Furthermore, Teva challenges the validity of a PTO regulation permitting extension of terminally disclaimed patents, 37 C.F.R. § 1.775(a).

In opposition, King argues that § 156 unambiguously states that a patent term "shall be extended" where conditions enumerated at § 156(a)(1)-(5), as here, are satisfied.[5] Moreover, argues King, § 156 does not prohibit the extension of a patent subject to a § 253 terminal disclaimer. King also argues that no conflict between § 156 and § 253 exists and that the PTO regulation permitting extension of terminally disclaimed patents is lawful. According to King, the '538 Patent has not yet expired and King has stated a claim.

B. Terminally Disclaimed Patents Are Not Barred from Obtaining a § 156 Extension

1. The Language of § 156

Because Teva challenges the legality of the § 156 extension of the '538 Patent's term, the Court first turns to the language of § 156. In construing a statute, the Court's first obligation "is to give effect to the intent of Congress." *Rabinowitz v. N.J. State Bd. of Educ.*, 550 F. Supp. 481, 486 (D.N.J. 1982). Because "Congress expresses its purpose by words," *id.*, "any inquiry as to the meaning of a statute must begin with its language." *Northview Motors, Inc. v. Chrysler Motors Corp.*, 227 F.3d 78, 93 (3d Cir. 2000); *see also Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999) ("As in any case of statutory construction, our analysis begins with the

[5] Teva has not argued that the enumerated conditions were not satisfied.

language of the statute. And where the statutory language provides a clear answer, it ends there as well.") (internal quotations and citation omitted). Furthermore, the Court must "take the statute as [it] find[s] it." *Anderson v. Wilson*, 289 U.S. 20, 27 (1933). Where the text of a statute is plain and unambiguous, "the sole function of the courts is to enforce it according to its terms." *Kay Berry, Inc. v. Terry Gifts, Inc.*, 421 F.3d 199, 204 (3d Cir. 2005). The Court must "faithfully construe what Congress has written and neither [] add nor [] subtract, nether [] delete nor [] distort." *See Rabinowitz*, 550 F. Supp. at 486 (internal quotations and citation omitted).

Section 156 states, *inter alia*:

> a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if--
> **(1)** the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;
> **(2)** the term of the patent has never been extended under subsection (e)(1) of this section;
> **(3)** an application for extension is submitted by the owner of record of the patent . . . ;
> **(4)** the product has been subject to a regulatory review period before its commercial marketing or use;
> **(5)(A)** except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; . . . .

35 U.S.C. § 156(a) (2005). As noted above, Teva has not alleged that the enumerated conditions were not satisfied. Instead, Teva argues that a § 156 patent term extension is not available to a patent subject to a § 253 terminal disclaimer. However, § 156 is plain and unambiguous: a terminally disclaimed patent is not barred from receiving a § 156 extension.

Section 156 plainly states that a patent satisfying the enumerated conditions "shall be extended." "The word 'shall' generally indicates a command that admits of no discretion on the

part of the person instructed to carry out the directive." *Assoc. of Civil Tech. v. Fed. Labor Rel. Auth.*, 22 F.3d 1150, 1153 (D.C. Cir. 1994). Thus, if the enumerated conditions are satisfied, the patentee is entitled to a term extension calculated pursuant to § 156.

Further, § 156 makes no reference whatsoever to terminal disclaimers. Section 156's direction that a patent term extension "shall" be granted if the conditions are met contains no exception for patents subject to a § 253 terminal disclaimer. This Court may not read language in or graft meaning on to § 156, and hence may not create an exception for terminally disclaimed patents where Congress did not see fit to do so. *See, e.g., Rabinowitz*, 550 F. Supp. at 486.

Moreover, as noted, Congress expressly listed conditions necessary for obtaining a § 156 patent term extension. 35 U.S.C. § § 156(a)(1)-(5) (2005). Applying the interpretative maxim *expressio unis est exclusio alterius* (the expression of one thing is the exclusion of the other), *see, e.g., U.S. v. State of New Jersey*, 194 F.3d 426, 429 (3d Cir. 1999), the Court concludes that the only limitations on the provision of a § 156 patent term extension are those expressly enumerated at § 156(a)(1)-(5). Nonexistence of a terminal disclaimer is not among those enumerated conditions, and, therefore, cannot be construed to be a condition for obtaining a § 156 patent term extension.

Accordingly, there is no textual basis in § 156 for making terminally disclaimed patents ineligible for a § 156 extension.

2. Comparison of § 156 and § 154(b)

Comparison of § 156 and 35 U.S.C. § 154(b), another provision in the patent law that provides for a patent term extension in specified circumstances, further supports the conclusion that § 156 does not bar terminally disclaimed patents from obtaining a § 156 extension. Whereas

§ 156 provides for a patent term extension for FDA delays in approving a drug for sale, § 154(b) provides for a patent term extension, or "adjustment," where a delay has occurred during prosecution of a patent before the PTO. 35 U.S.C. §§ 156, 154(b) (2005). Unlike § 156, § 154(b) expressly refers to terminally disclaimed patents: "No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer." 35 U.S.C. § 154(b)(2)(B) (2005). Section 154(b)(2)(B)'s language is plain and unambiguous: terminally disclaimed patents are barred from obtaining a § 154(b) patent term extension.

As an initial matter, § 154 demonstrates that Congress knows how to draft a clear exception barring a terminally disclaimed patent from receiving a patent term extension. Congress did not incorporate this language, or similar language, into § 156. Congress is generally presumed to "act[] intentionally and purposely when it includes particular language in one section of a statute but omits it in another[, which] presumption is made even stronger when, as here, Congress has amended a statute to include certain language in some, but not all, provisions of the statute." *United States v. Steiger*, 318 F.3d 1039, 1050-51 (11th Cir. 2003) (quotations and citations omitted). Congress's inclusion of this language in § 154(b) and its omission of such language in § 156 "strongly suggest a deliberate decision" not to include such an exception in § 156. *Key Tronic Corp. v. United States*, 511 U.S. 809, 818-19 (1994). Further, Congress amended both § 156 and § 154 in Pub. L. No. 103-465, § 532 (1994), in which Congress initially enacted § 154's exception for terminally disclaimed patents[6], and has amended

[6] Pub. L. No. 103-465, § 532 (1994) amended § 154 to state, *inter alia*:

(2) EXTENSION FOR APPELLATE REVIEW.--If the issue of a patent is delayed

both provisions several times since it enacted Pub. L. No. 103-465, § 532 (1994).[7] The Court thus may presume that Congress acted intentionally and purposely when it included an exception for terminally disclaimed patents in § 154 and omitted any exception for terminally disclaimed patents in § 156. *See Steiger*, 318 F.3d at 1050-51. Because Congress has carefully employed this exception § 154(b) and excluded it in § 156, it should not be implied where excluded. *Cf. Sundance Land Corp. v. Community First Federal Savings & Loan Assoc.*, 840 F. 653, 663 (9th Cir. 1988). Congress's silence in § 156 is controlling: § 156 does not bar terminally disclaimed patents from obtaining a § 156 patent term extension. *See In re Griffith*, 206 F.3d 1389, 1394 (11th Cir. 2000) ("[W]here Congress knows how to say something but chooses not to, its silence is controlling.")(quotations and citations omitted).

3. PTO Regulation § 1.775(a)

Further support for the conclusion that a terminally disclaimed patent is not barred from obtaining a § 156 extension is found in a nearly twenty-year old PTO regulation, 37 C.F.R. § 1.775(a) ("Regulation § 1.775(a)"). Regulation § 1.775(a) addresses the calculation of patent

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> due to appellate review by the Board of Patent Appeals and Interferences or by a Federal court and the patent is issued pursuant to a decision in the review reversing an adverse determination of patentability, the term of the patent shall be extended for a period of time but in no case more than 5 years. *A patent shall not be eligible for extension under this paragraph if it is subject to a terminal disclaimer due to the issue of another patent claiming subject matter that is not patentably distinct from that under appellate review.*

Pub. L. No. 103-465, § 532 (1994) (emphasis added).

[7] Congress amended both § 156 and § 154 in Pub. L. No. 103-465, § 532 (1994). Congress also amended § 156 in Pub. L. No. 105-115, § 125 (1997); Pub. L. No. 106-113, §§ 4404, 4732 (1999); Pub. L. No. 107-273, § 13206 (2002). Congress also amended § 154 in Pub. L. No. 104-295, § 20 (1996); Pub. L. No. 106-113, §§ 4402, 4504 (1999); and Pub. L. No. 107-273, §§ 13204, 13206 (2002).

term extensions for human drug products, and provides:

> If a determination is made pursuant to § 1.750 that a patent for a human drug, antibiotic drug or human biological product is eligible for extension, the term shall be extended by the time as calculated in days in the manner indicated by this section. The patent term extension will run from the original expiration date of the patent or any earlier date set by terminal disclaimer (§ 1.321).

37 C.F.R. § 1.775(a).[8] The relevance of Regulation § 1.775(a) to the Court's determination is not any persuasive value of the PTO's interpretation of the statute as such, but rather that the PTO has for nearly twenty years maintained the position that terminally disclaimed patent may obtain a patent term extension under § 156, and, despite several amendments to § 156 in the intervening years, Congress has never acted to change the PTO's interpretation or the pertinent language of § 156.

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[8] The PTO has confirmed its position that terminally disclaimed patents are eligible for § 156 extensions in the Manual of Patent Examining Procedure ("MPEP"), which, in the section addressing eligibility for § 156 patent term extensions, states:

> TERMINALLY DISCLAIMED PATENTS ARE ELIGIBLE
> A patent may be extended under 35 U.S.C. 156 even though it has been terminally disclaimed. A patent term extension under 35 U.S.C.156 is a limited extension of the patent rights associated with the approved product that is attached onto the original term of the patent. See 35 U.S.C. 156(b). Only one patent may be extended for a regulatory review period for any product, and 35 U.S.C. 156 sets the expiration date of a patent term extension. Although 35 U.S.C. 154(b)(2)(June 8, 1995) precludes a patent from being extended under 35 U.S.C. 154(b)if the patent has been terminally disclaimed due to an obviousness-type double patenting rejection (see MPEP § 2720), there is no such exclusion in 35 U.S.C. 156. Additionally, 35 U.S.C. 154(b)(2)(B)(May 29, 2000) provides that a patent cannot be adjusted beyond the date set by the disclaimer (see MPEP § 2730), but there is no similar provision in 35 U.S.C. § 156. Thus patents may receive a patent term extension under 35 U.S.C. § 156 beyond an expiration date set by a terminal disclaimer.

MPEP 2751, Rev.2, at 2700-30 (E8) (available at http://www.uspto.gov/web/offices/pac/mpep/documents/2700_2751.htm).

The parties do not appear to dispute that the Congress has not granted the PTO Commissioner substantive rulemaking authority, and thus that while Regulation § 1.775(a) may have the power to persuade under *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) and *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944), it is not entitled to deference under *Chevron USA, Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1989). Teva argues, citing the same concerns referenced above regarding double-patenting and legal effect of terminal disclaimers, that Regulation § 1.775(a) is invalid and thus unpersuasive. King responds that Teva's attack on Regulation § 1.775(a) is misplaced since the patent term extension at issue was based not on Regulation § 1.775(a), but rather on § 156, and because the PTO based Regulation § 1.775(a) on the conclusion that "there is no statutory basis for denying an application for patent term extension where the term of the patent sought to be extended is affected by a terminal disclaimer." 52 Fed. Reg. 9386-01 (March 24, 1987). The PTO's conclusion that there is no statutory basis for barring a terminally disclaimed patent from obtaining a § 156 extension is the same as arrived at independently by this Court, and thus the Court need not reach the issue of Regulation § 1.775(a)'s persuasiveness. Further, because Regulation § 1.775(a) to the extent challenged herein is not inconsistent with the Court's conclusion, the Court sees no basis on which to question its validity.

Regulation § 1.775(a) is relevant to the disposition of this action because, as noted, it has been extant for nearly twenty years without congressional intervention. Since the PTO promulgated Regulation § 1.775(a), Congress amended § 156 six times.[9] However, Congress has

[9] *See* Pub. L. No. 100-670, § 201 (1988); Pub. L. No. 103-179, §§ 5, 6 (1993); Pub. L. No. 103-465, § 532 (1994); Pub. L. No. 105-115, § 125 (1997); Pub. L. No. 106-113, §§ 4404, 4732 (1999); Pub. L. No. 107-273, § 13206 (2002).

never amended § 156 to undermine the PTO's interpretation of § 156 or to change § 156's language to bar terminally disclaimed patents from receiving a § 156 extension. The Court may presume "that Congress is knowledgeable about existing law pertinent to legislation it enacts." *VE Holdings Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574, 1581 (Fed. Cir. 1990). That Congress presumably was aware of the PTO's interpretation of § 156 and, despite amending § 156, "did nothing to change the interpretation or the statutory language on which it is based is persuasive evidence that the agency's prior interpretation was the one intended by Congress." *AD HOC Comm. v. United States*, 13 F.3d 398, 402 n.9 (Fed. Cir. 1994).

C. Section 253 Does Not Require Terminally Disclaimed Patents to Be Prohibited from Obtaining § 156 Patent Term Extensions

In an effort to circumvent the plain, unambiguous language of § 156, Teva argues that § 253 requires that § 156 not be construed as permitting a patent term extension for a terminally disclaimed patent. Section 253, however, does not compel a construction of § 156 inconsistent with the plain language discussed above.

Section 253 states:

> Whenever, without any deceptive intention, a claim of a patent is invalid the remaining claims shall not thereby be rendered invalid. A patentee, whether of the whole or any sectional interest therein, may, on payment of the fee required by law, make disclaimer of any complete claim, stating therein the extent of his interest in such patent. Such disclaimer shall be in writing, and recorded in the Patent and Trademark Office; and it shall thereafter be considered as part of the original patent to the extent of the interest possessed by the disclaimant and by those claiming under him.
>
> In like manner any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted.

35 U.S.C. 253 (2005). Nothing in the language of § 253 bars a terminally disclaimed patent from

obtaining a patent term extension. Thus, Teva's argument that the term of a patent terminally disclaimed pursuant to § 253 cannot be extended under § 156 has no support in the text of § 253.

To bolster its argument, Teva turns to the policies underlying and legal effects of § 253 terminal disclaimers. Teva discusses at length precedent concerning the fundamental patent law principle prohibiting double patenting as well as the proposition that an obviousness-type double patenting rejection of a patent application may be cured by the patent applicant by filing a § 253 terminal disclaimer that disclaims rights in the second application that would have extended beyond the expiration date of the original patent. *See, e.g., Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 940 (Fed. Cir. 1992). Teva argues that but for the terminal disclaimer curing the double-patenting problem, the second patent never would have been granted and § 156 cannot be used to "breathe life into a patent whose term had been deliberately shortened asa condition of its issuance." (Teva Br. at 14, 17). Further, Teva argues that the legal effect of a terminal disclaimer is to irrevocably dedicate to the public the disclaimed portion of the patent term and emphasizes that "such a disclaimer is final and irrevocable, and cannot be withdrawn or amended." (Teva Br. at 15; Teva Reply at 1). Teva argues that granting a § 156 extension to a patent subject to a § 253 terminal disclaimer would make those patents invalid due to double patenting and would "eviscerate[] the settled law prohibiting double patenting and the legal effect of a terminal disclaimer." (Teva Br. at 15; Teva Reply Br. at 1,4).

However, as discussed above, neither the terms of § 156 nor those of § 253 are consistent with Teva's argument. When the statutory text is clear, whatever merit Teva's "policy arguments may have, it is not the province of [courts] to rewrite the statute to accommodate them." *Swenger v. Chesney*, 294 F.3d 506, 518 (3d Cir. 2002) (quotations and citation omitted)

(alteration in *Swenger*). Congress did not elect to preclude a terminally disclaimed patent from obtaining a § 156 patent term extension. This Court cannot "amend or read into the statute by construction that which is not there." *Sandoz v. Chem. Works, Inc. v. U.S.*, 50 C.C.P.A. 31, 34 (C.C.P.A. 1963); *see also Rabinowitz v. N.J. State Bd. of Educ.*, 550 F. Supp. 481, 486 (D.N.J. 1982).

Further, while the Court is not unmindful of the policy implications Teva raises, the Court notes that Congress has previously enacted legislation the effects of which have been to alter the termination date of terminally disclaimed patents and to enlarge the time limits of a patentee's right to exclude. In support of its arguments, Teva emphasizes the principle that upon the expiration of the right to exclude conveyed by a patent, the public is free to use the invention as well as obvious modifications thereof. (Teva Br. at 10, 12). However, in the Uruguay Round Agreements Act ("URAA"), Congress altered the term of the patent owner's right to exclude from 17 years from issue date to 20 years from filing date, and allowed patents then in force to utilize the greater of the 20-year or the 17-year period. *See, e.g., Bayer AG v. Carlsbad Tech., Inc.*, 298 F.3d 1377 (Fed. Cir. 2002). The PTO concluded, and the Federal Circuit upheld, that the terms of such patents were automatically substituted for the later date by operation of the URAA. *Id.* Moreover, as both parties conceded at oral argument, § 156 makes possible that a patent granted a § 156 patent term extension could be in force for more than the statutory 20-year term. Thus Congress has, in the past, changed the term of a patent owner's right to exclude.

In addition, Congress previously provided for the alteration of the termination date of a terminally disclaimed patent. Where the expiration date of a terminally disclaimed patent had been linked to a patent the term of which, by operation of the URAA, was automatically

substituted for a later date, the expiration date of the terminally disclaimed patent was held to also automatically shift to that later date.[10] *See Bayer AG*, 298 F.3d at 1381-82.

Thus, Congress previously enacted legislation affecting the duration of the patent term and the termination date of terminally disclaimed patents.

V. CONCLUSION

For the reasons expressed above, the Court concludes that a terminally disclaimed patent is eligible for extension under 35 U.S.C. § 156. Consequently, the Patent Term Extension is valid and the '538 Patent will expire on June 6, 2008. Accordingly, Defendant's motion to dismiss is DENIED. An appropriate order will follow.

s/ Joel A. Pisano
JOEL A. PISANO, U.S.D.J.

DATED: January 20, 2006

[10] Notably, as referenced above, the termination date of the '538 Patent apparently was extended from June 3, 2002 to June 23, 2003 as a result of the URAA.